K073626

Bio-logic Systems
Special 510(k)
Master II Evoked Response System

December 21, 2007

PREMARKET NOTIFICATION [510(K)] SUMMARY

FEB - 5 2008

Trade Name: Master II Evoked Response System

Common or Usual Name: Evoked Response Auditory Stimulator

Classification Name and Number: stimulator, auditory, evoked response 882.1900

Classification Name: stimulator, auditory, evoked response (per 21 CFR section 882.1900)

Manufacturer's Name: Bio-logic Systems
One Bio-logic Plaza
Mundelein, IL 60060

Corresponding Official: Nicohl Wilding
Director Quality Assurance and Regulatory Affairs
One Bio-logic Plaza
Mundelein, IL 60060
Telephone Number: 800-323-8326 ext. 267
Fax Number: 847-949-8615

Predicate Device(s): K021895 Master, a Modification to Bio-logic Evoked Potential

Device Description: Master II Evoked Response System is a Windows® based software application for use with the Navigator Pro hardware platform using Auditory Steady State Response Modality for the recording and analysis of human physiological data for the purpose of neurological diagnosis and treatment of audiovestibular and hearing related disorders.

Intended Use: The Master II Evoked Response System is intended for the recording and analysis of human physiological data necessary for the diagnosis of audiovestibular and hearing-related disorders.

Technological Characteristics: Master II is a Windows® based application using Auditory Steady State Response (ASSR) modality. ASSR is used to predict frequency-specific behavioral hearing thresholds particularly for patients who cannot provide a reliable behavioral response. The ASSR technique uses a continuous frequency and/or amplitude modulated tone as the stimulus and can combine several stimuli together

simultaneously to assess responses to various frequencies all at the same time. The evoked response recorded from scalp electrodes is reflective of the frequency of the modulation envelope of the stimulus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2008

Bio-logic Systems Corp.
% Ms. Nicohl Wilding
One Bio-logic Plaza
Mundelein, IL 60060

Re: K073626
Trade/Device Name: Bio-Logic Master II Evoked Response System
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: January 21, 2008
Received: January 23, 2008

Dear Ms. Wilding:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: _____

Device Name: Master II Evoked Response System

Indications for Use:
The Master II Evoked Response System is intended for the recording and analysis of human physiological data necessary for the diagnosis of audiovestibular and hearing-related disorders.

☒ **Prescription Use** and/or ☐ **Over-The-Counter Use**
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073626